EPA Registration 91300-3

PROCESSING REQUEST

Reg # 91300-3 **Decision # 506519**

Description: new product

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
X Dated: 12/10/17/2015		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

X New CSF(s) Dated: 10/6/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jacquelyn Marchese

Division: RD

Phone: 703-347-0559

Date: 12/10/18/2015

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
91300-3	12/17/15

Term of Issuance:
Conditional, Time-Limited
Expires: 12/17/2017

Name of Pesticide Product:
Torc Duo for Cats

Name and Address of Registrant (include ZIP Code):

Promika, LLC
c/o Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St., NW, Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date: 12/17/15

EPA Form 8570-6

2. This registration is time-limited and expires 12/17/2017.

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:

    - EPA Registration Number
    - Product name (brand name)
    - Lot #
    - Where purchased: internet, store, veterinarian
    - Active Ingredient(s)
    - Weight range for product
    - Date on which incident occurred (mm/dd/yyyy)
    - State in which the incident occurred (standard 2 letter abbreviation)
    - Registrant case #
    - Species: dog, cat, other (specify)
    - Breed: (as reported by pet owner)
    - Age: months or years
    - Sex: M, F, or neutered
    - Weight: pounds
    - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
    - Body System: neurological, dermatological, GI, respiratory, ocular, other
    - Major signs noted with separate column for each sign, using standard terminology
    - Time to Onset: (hours, days)
    - Treated by veterinarian: yes or no
    - First time product used: yes or no
    - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
    - Any known precondition
    - EPA Severity Code: death, major, moderate, minor
    - Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

    - All incidents should be reported including all minor dermal and ocular irritation reports.
    - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:

   a. Imidacloprid GDCI-129099-951
   b. Pyriproxyfen GDCI-129032-1299
   c. Imidacloprid EDSP-129099
   d. Pyriproxyfen EDSP- 129032

   You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

7. Make the following label changes before you release the product for shipment:

   - Revise the EPA Registration Number to read, "EPA Reg. No. 91300-3."

8. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/06/2015

If you have any questions, please contact Jacquelyn Marchese by phone at 703-347-0559, or via email at marchese.jacquelyn@epa.gov.

Enclosure

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

[Front Panel]

TORC™ DUO FOR CATS

A Liquid Topical Flea Product for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.]

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See [back] [side] [other] [panel] for FIRST AID and PRECAUTIONARY STATEMENTS]
Refer to Package Insert for Directions for Use, Storage and Disposal, and First Aid.

NET CONTENTS: X fl. oz.
[Picture of a cat in appropriate weight range on front panel to be included]

[For use ONLY on cats 8 weeks of age and older and weighing 2 to 5 lbs.:] [4] tube(s), each 0.0078 fl. oz.
[For use ONLY on cats 8 weeks of age and older and weighing 5 to 9 lbs.:] [4] tube(s), each 0.014 fl. oz.
[For use ONLY on cats 8 weeks of age and older and weighing over 9 lbs.:] [4] tube(s), each 0.027 fl. oz.

EPA Reg. No. 91300-NEW
EPA Est. No. XXXXX-XX-X

[Manufactured for:]
[Distributed by:]
Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

[Back Panel]

TORC™ DUO FOR CATS

A Liquid Topical Flea Product for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing [2 – 5 lbs][5-9 lbs][Over 9 lbs]

READ THE ENTIRE LABEL BEFORE EACH USE

FIRST AID	
If Swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Do not give any liquid to the person. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If In Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If On Skin:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 - 20 minutes. • Call a poison control center or doctor for treatment or advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-844-685-9173.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external Use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than [2 lbs.] [5 lbs.] [9 lbs.]. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide products for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

Side Effects: Monitor your cat after application. Side effects, although very rare, may include signs of skin irritations such as redness, scratching, or other signs of discomfort.
Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-844-685-9173.

[Sample – Not for (Re)Sale]

[Manufactured for:]
[Distributed by:]
Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560
[Made in the USA]

[Back Panel and/or Insert]

TORC™ DUO FOR CATS

A Liquid Topical Flea Product for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.]

READ THE ENTIRE LABEL BEFORE EACH USE
Prevent and Treat Flea Infestations

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. To prevent harm to you and your cat, read the entire label and package insert before each use. Follow all directions and precautionary statements carefully. Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.].

RESTRICTIONS:

- Use only on cats or kittens 8 weeks and older and weighing more than [2 lbs.] [5 lbs.] [9 lbs.].
- Do not apply to cats or kittens less than 8 weeks old and weighing less than [2 lbs.] [5 lbs.] [9 lbs.]
- Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger cats.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do not treat more than [one] [1] cat per tube.
- Do not exceed labeled dosage amount for cats.

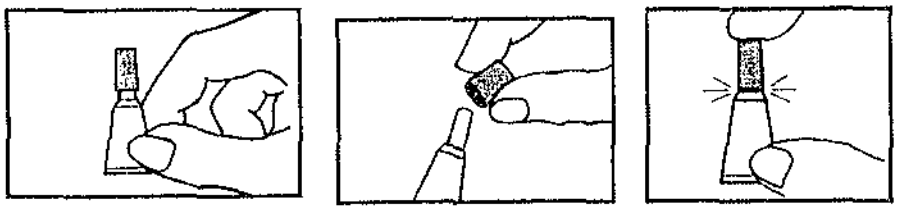
HOW TO OPEN
[OPTION 1:]

1. Being careful not to cut close to the blister cavities take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

APPLICATION INSTRUCTIONS:
[Visuals Depicting How to Open Applicator Tube and Application to Animal]



HOW TO APPLY

[OPTION 1:]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes, or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

[OPTION 2:]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
3. Twist dispensing tip clockwise about half (½) turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes, or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

TORC™ DUO FOR CATS kills fleas on cats within 12 hours, which may reduce the incidence of flea allergy dermatitis (FAD) or flea bite hypersensitivity. This product prevents further flea infestation for four weeks by killing reinfesting fleas within 2 hours.

TORC™ DUO FOR CATS kills fleas, eggs and larvae and effectively controls all flea life-cycle stages for control of flea populations.

TORC™ DUO FOR CATS is waterproof and is effective on your cat, even after shampoo treatment, swimming or exposure to rain or sunlight.

To prevent further flea infestation, use TORC™ DUO FOR CATS monthly.

Use monthly to control and prevent fleas.

[OPTIONAL GRAPHICS/ICONS/PICTURES – COLOR MAY CHANGE]

[For Chemical Emergency, Spills, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night within USA and Canada: 1-800-424-9300 CCN712312 or +1 703-527-3887 (collect calls accepted)]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. **Pesticide Disposal and Container Handling:** Nonrefillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES,** and **LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Promika, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Promika, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Promika, LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Promika, LLC disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Promika, LLC election, the replacement of product.]

[Label on Individual Tube]

TORC™ DUO FOR CATS

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]

2 to 5 lbs. - 0.0078 fl. oz. ≥ 8 wks
5 to 9 lbs. - 0.014 fl. oz. ≥ 8 wks
Over 9 lbs. - 0.027 fl. oz. ≥ 8 wks

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN
CAUTION
Read Entire Label Before Use

EPA Reg. No. 91300-NEW
[Lot No. is heat stamped in tube crimp – required on each]

NOTE TO REVIEWER: [(Brackets and parentheses indicated alternate language)]

OPTIONAL MARKETING CLAIMS [May appear on any panel/insert]

[Fleas]

- Kills fleas (Ctenocephalides sp.) on your cat and in its environment
- Kills fleas
- Month long flea protection
- Kills fleas within 12 hours of application
- Kills fleas for up to [4 weeks] [1 month]
- Kills fleas which may cause flea allergy dermatitis and flea bite anemia
- Effective against fleas that may cause flea allergy dermatitis and flea bite anemia
- Kills fleas that may cause transmission of tapeworms
- TORC™ DUO FOR CATS is effective for the prevention of new infestations and treatment of fleas on cats
- Prevent further flea infestations for [4 weeks] [1 month]
- Protects against reinfesting fleas for [4 weeks] [1 month] [30 days]
- Kills fleas on cats within 12 hours to prevent infestations for [4 weeks] [1 month]
- Kills fleas before they lay eggs
- Kills all larval stages of fleas
- Targets all life stages of fleas
- [Prevents] [Stops] flea eggs and flea larvae from developing into biting adults
- Breaks the flea life cycle
- Triple flea protection: kills adults, larvae, and eggs

- Flea adulticide, larvicide, and ovicide
- Multi-stage flea control—egg, larvae, adult
- Flea protection
- Controls existing fleas and flea eggs to prevent future flea infestations
- The Insect growth regulator (IGR) kills flea eggs and prevents reinfestation

[Other]

- Only for use on cats and kittens 8 weeks of age and older and weighing more than [2 lbs.] [5 lbs.] [9 lbs.]
- TORC™ DUO FOR CATS contains imidacloprid [, in conjunction with [an/the] [insect growth regulator] [IGR] [pyriproxyfen]]
- One topical application remains effective for [4 weeks] [a month]
- Convenient topical solution
- Easy-to-apply [monthly] [topical solution]
- Use monthly for best results year round
- A monthly topical application for cats 8 weeks of age or older and weighing more than [2 lbs.] [5 lbs.] [9 lbs.]
- Starts working through contact
- Remains effective after bathing and/or swimming
- Continues to kill fleas even if your cat gets wet
- Water resistant
- Waterproof
- Fragrance-free
- Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Advantage® II Cat
- Advantage® II is a registered trademark of Bayer Healthcare LLC Animal Health Division
- TORC™ DUO FOR CATS is not manufactured, or distributed by Bayer Healthcare LLC Animal Health Division, seller of Advantage® II Cats
- Apply monthly [every 30 days] [every 4 weeks]
- Convenient [applicator]
- Easy to use [applicator]
- Direct to your cat's skin
- Simple to [handle/apply]

Pages 14-16 Claimed confidential by submitter

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☒ Registration ☐ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: **91300-NEW**
2. EPA Product Manager: **Venus Eagle**
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): **Promika, LLC / Torc™ Duo for Cats**
5. PM # **1**
5. Name and Address of Applicant *(Include ZIP Code)*: **Promika, LLC, 1204 Village Market Place, #273, Morrisville, NC 27560**
☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. 2596-181
Product Name Hartz® Reference # 146

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated 4-15-2015
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA3 R301: Promika, LLC is submitting a registration application for a new end-use product containing Imidacloprid (9.1%) and Pyriproxyfen (0.46%) for cats, which is 100% compositionally identical to a registered product.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No		☐ Yes ☒ No		☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) Plastic Bag
***Certification must be submitted**	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	
	0.0078 fl. oz., 0.014 fl. oz., 0.027 fl. oz.	1, 2, 3, 4, 5, 6 tubes			

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: Various (see above)
5. Location of Label Directions: ☐ On Can ☒ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☒ Other Printed on carton ☒ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Brooke Hedrick	Regulatory & Project Management	919-946-8294

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature BY: Brooke Hedrick
3. Title: Regulatory & Project Management
4. Typed Name: Brooke Hedrick
5. Date: June 29, 2015

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Promika, LLC
1204 Village Place, #273
Morrisville, NC 27560

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new end-use product, Torc™ Duo for Cats (EPA Reg. No. 91300-NEW).

SUBMITTAL DATE:

June 29, 2015

Volume	Study Title	MRID No.
1	Administrative Materials	49658400
2	Group A Product Chemistry for Torc™ Duo for Cats (91300-NEW); Cowen, N. (2015); EPA Guidelines OCSPP 830.1550; 830.1600; 830.1620; 830.1650; 830.1670; 830.1750.	49658401

8/10/2015 - the product's cited efficacy studies do not match what is cited on the me-tooed product (2596-181), therefore on Venus's instruction, it was sent to Steve Schaible to be recoded to R315. This is associated with 91300-E, which will also be recoded.

Went back and forth with the consultant, James Messina - he doesnt want the R315 code but wants to cite another study that isnt on the me-tooed product for an IGR claim.

9/1 - discussion with Steve Schaible, if he wants that MRID he needs to have the 315 code. Steve will talk to Venus and hopefully get this sorted today3

9-18 - new agent is Ann Tillman/Pyxis. Ann will send over a revised data matrix in order to have the R301 code.

Promika

September 11, 2015

To Whom It May Concern: RE: Letter of Authorization Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruette, Janelle Kay of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Promika, LLC (EPA Company Number 91300), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Randall V Canady
Chief Executive Officer
Promika, LLC

cc: Pyxis Regulatory Consultants, Inc.

Marchese, Jacquelyn

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Friday, October 02, 2015 11:08 AM
To: Marchese, Jacquelyn
Cc: Eagle, Venus
Subject: Torc Duo for Cats, Torc Duo for Dogs PRIA Extension Request

Jacquelyn,

Promika LLC requests that the PRIA due date for the two actions listed below be extended to December 23, 2015.

Torc Duo for Dogs, EPA File Symbol 91300-E, Decision No. D-506518

Torc Duo for Cats, EPA File Symbol 91300-G, Decision No. D-506519

Thanks very much!

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 506518	Registration #: 91300-E	Petition #:
506519	91300-G	

☐ *See page 2 for additional registration entries*

Chemical Name: pyriproxyfen, imidacloprid

Fee Category: R301	**PRIA Decision Time Frame:** 4 months	
Submitted by: Jacquelyn Marchese	**Branch:** OCSPP/OPP/RD	**Date:** 10/05/2015

Company: Promika

Original PRIA Due Date: 11/23/2015	**Proposed New PRIA Due Date:** 12/23/2015

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☑ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☑ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

Original consultant did not want to change the data matrix to match the 'me-tooed' product but wanted to keep the R301 with mismatched data matrices.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

8/20/15, 8/28, 8/31, 9/1, 9/8 - Email from EPA to consultant. 8/26, 8/27, 8/28, 8/31, 9/1, 9/1, 9/3, 9/8 - Email from consultant to EPA. 8/27 - RM and PM took issue to PRIA meeting. 8/27, 9/8 - Call with consultant, EPA. 9/14 - EPA received notice that a new consultant is hired. 9/14 - Call with EPA and new consultant. 9/18 - New data matrix received.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: Will give more time for RD review

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature:	**Date:**

Decision #: 506518	Registration #:91300-E	Petition #:
506519	91300-G	

Issue(s) (describe in detail):

The original consultant wanted the two products to be coded as an R301, but the data matrices did not match the data matrices on file for the me-tooed products. Through FOIA, the consultant had access to the data matrices of the me-tooed products but refused to revise the data matrices of the new products to match the other data matrices. This discussion with the registrant spanned 3 weeks and in that time all other work on these products was put on hold. Since then, a new consultant has been hired and new data matrices (suitable for a R301 code) have been submitted. The registrant has agreed to a one month renegotiation to give EPA time to review the package as a me-too PRIA action.

Comment(s):

This issue with this action was that the consultant did not agree to the PRIA code. No other deficiencies of this package have been found.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-15278131229-JM

SUBMITTED on 10/05/2015 at 02:06:58 PM by CN=Jacquelyn Marchese/OU=DC/O=USEPA/C=US

APPROVED on 10/05/2015 at 03:36:13 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 10/05/2015 at 04:05:07 PM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 10/06/2015 at 06:45:30 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

UNITE TATES ENVIRONMENTAL PROTI ION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 15, 2015

Promika, LLC
c/o Ann M. Tillman, Ph.D.
Agent
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: PRIA R301 – New Pet Spot-On Products
Product Name: Torc Duo for Cats, Torc Duo for Dogs
EPA Registration Number: 91300-G, 91300-E
Application Date: 6/29/2015
Decision Number: 506519, 506518

Dear Dr. Tillman:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

(a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
(b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
(c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Jacquelyn Marchese at marchese.jacquelyn@epa.gov or at 703-347-0559.

Sincerely,

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Attachments: Proposed Label - Torc Duo for Cats_6-26-2015_EPA Edits.pdf
Proposed Label - Torc Duo for Dogs_6-26-2015_EPA Edits.pdf

Decision #: 506519
DP #: (429429)
PRIA
Parent DP #:
Submission #: 970511
E-Sub #: 7991

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2015

* * * Registration Information * * *

Registration: 91300-G - Torc Duo for Cats

Company: 91300 - PROMIKA, LLC

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7228

Risk Manager Reviewer: Jacquelyn Marchese JMARCHES

Sent Date: _____ PRIA Due Date: ~~23-Nov-2015~~ 12/23/15 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R301) NEW PRODUCT;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND I

Ingredients: 129099, Imidacloprid(9.1%)

129032, Pyriproxyfen(.46%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 05-Oct-2015 Due Back: _____

DP Ingredient: 129032, Pyriproxyfen

129099, Imidacloprid

DP Title: Product Chemistry

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

Assigned To	Date In	Date Out
Organization: RD / CITAB		
Team Name: CHEM		
Reviewer Name:		
Contractor Name:		

11/13/15

Last Possible Science Due Date: ~~24-Sep-2015~~

Science Due Date: _____

Sub Data Package Due Date: _____

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product Chem,
Pleave review the submitted studies and CSF in support of the new pet spot on product Torc Duo for Cats (91300-G) and note that this action have been coded an R301 - it should have the exact same data matrix, label and CSF as the me-tooed product 2596-181. I have included the data matrix, CSF, cover letter and label of the proposed product along with the data matrix, CSF, label, and p.c. review of the me-tooed product. Please let me know if there are any discrepancies or if you have any questions.

Thank you,
Jackie
marchese.jacquelyn@epa.gov
703-347-0559

DP#: (429429) *** Studies Sent for Review *** Decision#: (506519)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49287703		McGarvey, E. (2013) Product Chemistry Enforcement Analytical Method [Hartz Reference 146]. Unpublished Study Prepared by the Hartz Mountain Corporation. 49p. [DUPLICATE OF MRID 49287903]	830.1800/Enforcement analytical method	Pass (07-Apr-2014)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.6302/Color	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.6303/Physical state	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.6304/Odor	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.6315/Flammability	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.7000/pH	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.7100/Viscosity	Not Reviewed (02-Jul-2015)
49658202		Bradbury, R. (2015) Product Chemistry: Physical and Chemical Characteristics. Project Number: ECS/355/1. Unpublished study prepared by EcoSafe Natural Products, Inc. 7p.	830.7300/Density/relative density	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1550/Product identity and composition	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1600/Description of materials used to produce the product	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1620/Description of production process	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1650/Description of formulation process	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1670/Discussion of formation of impurities	Not Reviewed (02-Jul-2015)
49658401		Cowen, N. (2015) Group A Product Chemistry for Torc(TM) Duo for Cats. Project Number: PROMIKA/062015A. Unpublished study prepared by Promika, LLC. 78p.	830.1750/Certified limits	Not Reviewed (02-Jul-2015)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

Revised
DP BARCODE No.: 429429; **FILE SYMBOL No.**: 91300-G (screen); **PRODUCT NAME**: Torc Duo for Cats; **DECISION No.**:506519; **PC Code(s)**:129099, 129032; **ACTION CODE**: R301; **FOOD Use**: No

DATE OUT: October 6, 2015

SUBJECT: End Use Product Chemistry Review
Product Name: Torc Duo for Cats

FROM: Shyam Mathur
Product Chemistry Team Leader
CITAB/RD (7505P)

TO: Jacquelyn Marchese / Venus Eagle, RM 01
I-V Branch 3 / RD (7505P)

Company Name: Promika LLC
Formulation Type: Insecticide
MRID No(s).: 49658401, 49658202 and cited 49287703

CONCLUSION:

Deficiencies: Yes
(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted

Group B: All required data submitted

CSF: Basic CSF (dated 06-26-2015) submitted.
Note 1: The values of pH (830.700) & Flash point (830.6315) given in Box #8 and Box #9 respectively of the proposed CSF do not concur with those provided in the group B product chemistry data submitted under MRID No. 49658202.
pH in the CSF = 6.70; pH in the Data = 4.64
Flash point in CSF = 169°F; Flash point in the PC data = >200°F
The registrant must correct the CSF.

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DP BAR CODE NO.: 429429 **EPA File Symbol NO.: 91300-G** **DECISION NO.: 506519**
PC Code: 129032,129099 **ACTION CODE: R301**
FOOD Use: No

DATE OUT: 10/07/2015

SUBJECT: End Use Product Chemistry Review
Product Name: Torc Duo for Cats

FROM: Hari Mukhoty, DVM, PhD.
Product Chemistry Team
CITAB / Registration Division (7505P)

10-15-15

TO: Jacquelyn Marchese, RMR / Venus Eagle, RM 01
Vertebrate & Invertebrate Branch 3 / Registration Division (7505P)

Company Name: Promika, LLC
Formulation Type: Not Provided

INTRODUCTION:

The registrant has proposed a basic CSF (Dated: 10/06/2015) and also has proposed a product specific label for registration of the aforesaid product under EPA File Symbol No. 91300-G.

The product chemistry data have been submitted under MRIDs: 496584-01, 496582-02, and 492877-01 & 03.

CITAB has been requested to evaluate the product chemistry data required for registration of the proposed formulation.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Imidacloprid (9.10.0%) and Pyriproxyfen (0.46%)..

2. Has the registrant claimed substantial similarity to registered product? [X] Yes [ ] No [ ] NA If yes: EPA Reg. No. 2596-181. The registrant claims that the proposed product is 100% compositionally identical to the cited product.

3. The source material of the active ingredient is registered with the Agency [Yes].

4. The CSF has not been screened by inert group. However, the inerts are approved for non-food use.

5. Confidential Statement of Formula(s):

[X] Basic -	Dated: 06/26/2015	Re-submitted: 10/06/2015
[ ] Alternate -	Dated:	Re-submitted: NA

Alternate CSF(s) complies with 40CFR §152.43: [X] Yes [ ] No NA [ ].

6. Product label

a. Ingredient statement: Nominal concentrations of AI listed on CSF(s) concur with product label (PR Notice 91-2).

[Yes]

Is the sub statement in compliance with PR Notice 97-6?

[X] Yes [ ] No - Uses the term "Other Ingredients"

, if not, explain below:

Metallic equivalent:	[ ] Yes [X] NA
Soluble arsenic:	[ ] Yes [X] NA
Isomeric ratios:	[ ] Yes [X] NA
Acid equivalent:	[ ] Yes [X] NA

b. Health related sub statements:

Petroleum distillate at > 10%:	[ ] Yes [ ] No [X] NA
Methanol at > 4%:	[ ] Yes [ ] No [X] NA
Sodium Nitrate / Sodium Nitrite	[ ] Yes [ ] No [X] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown? Reacts with atmospheric water to product phosphine gas.

[ ] Yes [X] No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): [ ] Yes [X] No [ ] NA

d. Label requires an additional Storage and Disposal statement: [ ] Yes [X] No

Final decision of overall label acceptance will be made by the PM.

7. Group **A**: Product Chemistry Data

CITAB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	496584-01
830.1600	Description of materials used to produce the product			"	A	"
830.1650	Description of formulation process			"	A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			NR	NR	
830.1750	Certified limits (158.350)	Standard certified limits				CLs are standard MRID: 496584-01. Also See CSF dated 10/06/2015
		Proposed Limits	X		A	
		Justification for wider limits	X		A	
830.1800	Enforcement analytical method #		X		A	MRID: 492877-03.

A = Acceptance, NR = Not Required, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Acceptable
# Analytical Method: HPLC method was used with UV detector set at 254 nm. Validation data for accuracy, linearity, repeatability were provided.

8. Group **B:**

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid – Clear, Light yellow color	A	496582-02
830.6314	Oxidation/reduction	Does not contain an oxidizing or reducing agent	A	492877-01
830.6315	Flammability	Flash point > 200 ° F	A	496582-02
830.6316	Explodability	It is not potentially explosive	A	492877-01
830.6317	Storage stability		In Progress	496582-02
830.6319	Miscibility	It is not diluted with end use product	A	492877-01
830.6320	Corrosion characteristics		In Progress	496582-02
830.7000	pH	4.64	A	"
830.7100	Viscosity	4.46 mPa	A	"
830.7300	Density	1.161 g/ml	A	"
830.7520	Particle size	NA because it is a liquid		

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

DP BAR CODE NO.: 429426 **EPA File Symbol NO.: 91300-E** **DECISION NO.: 506518**
PC Code: 129032,129099 **ACTION CODE: R301**
FOOD Use: No

CONCLUSIONS:

1. CITAB has reviewed the CSF (Dated: 10/06/2015) for the proposed basic formulation and finds it to be acceptable. The CSF is attached with this review and can be located in OPPIN CHEM DOCS.

2. Product chemistry Group A and Group B data, with the exception of Storage stability (830.6317) and Corrosion characteristics (830.6320) data are satisfied and acceptable. Storage stability (830.6317) and Corrosion characteristics (830.6320) studies are in progress.

3 . The accepted label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.

Decision #: 506519
DP #: (429462)
PRIA
Parent DP #:
Submission #: 970511
E-Sub #: 7991

DATA PACKAGE BEAN SHEET

Date: 06-Oct-2015

* * * Registration Information * * *

Registration: 91300-G - Torc Duo for Cats

Company: 91300 - PROMIKA, LLC

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7228

Risk Manager Reviewer: Jacquelyn Marchese JMARCHES

Sent Date: _____ PRIA Due Date: ~~23-Nov-2015~~ 12/23/15 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R301) NEW PRODUCT;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND I

Ingredients: 129099, Imidacloprid(9.1%)

129032, Pyriproxyfen(.46%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 06-Oct-2015 Due Back: _____

DP Ingredient: 129032, Pyriproxyfen

129099, Imidacloprid

DP Title: Companion Animal

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out	
Organization:	RD / CITAB			Last Possible Science Due Date: ~~24-Sep-2015~~ 11/13/15
Team Name:	Companion Animal Team			Science Due Date:
Reviewer Name:	Backus, Byron			Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Byron,
Pleave review the submitted studies and CSF in support of the new pet spot on product Torc Duo for Cats (91300-G) and note that this action have been coded an R301 - it should have the exact same, label and CSF as the me-tooed product 2596-181 and did a cite all for companion animal. I have included the data matrix, CSF, cover letter and label of the proposed product along with the data matrix, CSF, label, and companion animal study of the me-tooed product. Please let me know if there are any discrepancies or if you have any questions.

Thank you,
Jackie
marchese.jacquelyn@epa.gov
703-347-0559

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

October 13, 2015

MEMORANDUM

Subject:	Name of Pesticide Product:	TORC™ DUO FOR CATS
	EPA Reg. No. /File Symbol:	91300-G
	DP Barcode:	DP 429462
	Decision No.:	506519
	Action Code:	R301
	Submission#:	970511
	E-Sub#:	7991
	PC Code:	129099 (Imidacloprid: 9.1%)
		129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus Oct 13, 2015

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

JCR

To: Jacquelyn Marchese/Venus Eagle RM 01
IVB3
Registration Division (7505P)

Registrant: PROMIKA. LLC
1204 Village Market Place, #237
Morrisville, NC 27560

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
Other Ingredient(s):	90.44%
TOTAL	100.00%

ACTION REQUESTED: "Please review the submitted [cited?] studies and CSF in support of the new pet spot on product Torc Duo for Cats (91300-G) and note that this action has been

coded an R301 – it should have the exact same label…as the me-tooed product 2596-181 and did a cite-all for companion animal [safety studies]. I have included the data matrix, CSF, cover letter and label of the proposed product along with the data matrix, CSF. label, and companion animal study of the me-tooed product…"

COMMENTS AND RECOMMENDATIONS:

1. According to the Application for Pesticide Registration form (signed and dated June 29, 2015) the registrant is asking for an expedited review, stating that this product is similar or identical in composition and labeling to EPA Reg. No. 2596-181.

2. The proposed dosage levels are 0.0078 fl. oz. [0.23 mL] for cats weighing 2 to 5 lbs (with the stipulation that this product is not to be applied to cats weighing less than 2 lbs); 0.014 fl. oz. [0.4 mL] for cats weighing 5 to 9 lbs; and 0.027 fl. oz. [0.8 mL] for cats weighing more than 9 lbs. From the CSF the density is 9.7 lbs/gallon [1.163 g/cm^3] so a dosage level of 0.23 mL on a 2 lb (0.9072 kg) cat would be a dosage of 26.8 mg imidacloprid/kg; a dosage level of 0.4 mL on a 5 lb (2.268 kg) cat would be a dosage of 18.7 mg imidacloprid/kg; and a dosage of 0.8 mL on a 9 lb (4.082 kg) cat would be a dosage of 20.7 mg imidacloprid/kg. Labeling includes the statement that the product can be applied every seven days in case of severe flea infestation. ✓

2. The registrant has not cited any specific companion animal safety studies (the data matrix dated September 15, 2015 simply has "cite-all" for the 870.7200 Guideline Reference Number). A search of the submitted studies indicates there are apparently only two studies, MRIDs 44157302 and 47924801 (for 47924801 there is additional material in 48085101) that can be used to satisfy the 870.7200 data requirement for 91300-G.

3. The study in MRID 44157302 [Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p.] was reviewed by HED (TXR 0012322, memorandum from Virginia Dobozy dated September 24, 1997). The following is from the executive summary:

   "In a domestic animal safety study (MRID # 44157302), six 8 week-old kittens/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 ml) at weekly intervals for eight treatments. Six kittens/sex were treated with the vehicle control at the recommended use rate (0.4 ml) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 8 week-old kittens can tolerate a dose of 5X the recommended use rate.

   "The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study."

   The initial body weights of the twelve 5X kittens are reported on page 8 of MRID 44157302; the 4 lowest weight males (0.73, 0.73, 0.83 and 0.84 kg) and 4 lowest weight females (0.82, 0.82, 0.85, 0.85 kg) had a mean weight of 0.81 kg . Since each was treated with 2.0 mL of a formulation containing 9.1% imidacloprid, they were each exposed to 207 mg imidacloprid which, divided by 0.81 kg, results in a mean of 256 mg/kg (207 mg ÷ 0.81 kg). **This study supports a dose rate of 256 mg/kg ÷ 5 = 51.1 mg/kg, which is greater than (and supports)**

the proposed maximum dosage rates for 91300-G (0.23 mL on a 2 lb cat = 26.8 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18.7 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20.7 mg imidacloprid/kg). In addition, since the kittens were treated weekly, this study supports a retreatment interval of seven days if there is a severe flea infestation.

The test material in MRID 44157302 did not include Pyriproxyfen (Nylar); however, pyriproxyfen has been demonstrated to have low acute toxicity to mammalian species, and it is present in 91300-G at less than 1%, so that the acute toxicity from the active ingredients in 91300-G is from the imidacloprid, so that 44157302 can be used to satisfy the 870.7200 (cat and kitten) data requirement.

4. The study in MRID 47924801 [Madsen, T. (2009) Evaluation of the General Safety of M880. Project Number: 152/141, S07648, 33714. Unpublished study prepared by Sinclair Research Center, Inc. 193 p.] was reviewed by TRB (TXR 5012077, memorandum dated April 15, 2010 from B. Backus). The following is excerpted from the executive summary:

"In a companion animal safety study (MRID 47924801), 5 groups, each containing 6 males and 6 females, of domestic shorthair kittens (54-57 days old on Day 0; Day -1 body weights: males: 0.691-1.012 kg; females: 0.555-0.935 kg; source: Liberty Research, Inc., Waverly, NY), were topically treated (on Day 0) with (Group 1): mineral oil at a total dose of 1.15 mL; (Group 2): 3X vehicle substance at a total dose of 0.63 mL; (Group 3): 5X vehicle substance at a total dose of 1.05 mL; (Group 4): 3X test substance at a total dose of 0.69 mL; and (Group 5): 5X dose test substance at a total dose of 1.15 mL...

"The groups and test materials they received (with amounts applied) are shown in the table below:

Group	Test Material Applied	Volume of each application	Cumulative amount applied on Day 0; also on Day 14
1	Mineral oil	1st app = 0.35 mL; 2nd & 3rd = 0.4 mL	1.15 mL
2	Vehicle of proposed formulation (no active ingredients) at 3X	3 applications @ 0.21 mL	0.63 mL
3	Vehicle of proposed formulation (no active ingredients) at 5X	3 applications @ 0.35 mL	1.05 mL
4	Proposed formulation (with active ingredients) at 3X	3 applications @ 0.23 mL	0.69 mL
5	Proposed formulation (with active ingredients) at 5x	1st app = 0.35 mL; 2nd & 3rd = 0.4 mL	1.15 mL

"All animals survived to the end of the study...

"It is concluded that the margin of safety in kittens administered topical application of the product formulation is at least 3X. Possible effects observed at 5X included lethargy in one male kitten following the second set of applications, and decreased body weight gains in both males and females in the period from day -1 to day 20. As noted in the current 870.7200 Guidelines: "Consideration will be given to products with less than a 5X margin of safety, depending on the severity of clinical signs of toxicity (e.g. transient, non-life-threatening signs).

"This companion animal safety study in male and female domestic shorthair kittens is **Acceptable/Guideline** and **does satisfy** the guideline requirement for a companion animal safety study (OPPTS 870.7200) in 54-57 day (8 week) kittens."

Individual body weights for MRID 47924801 are reported on page 89 for males and page 90 for females. Individual day -1 bodyweights for group 5 (5X) males were 1.012, 0.881, 0.777, 0.857, 0.889 and 0.762 kg, and for group 5 (5X) females were 0.935, 0.786, 0.613, 0.746, 0.762 and 0.792 kg. The mean weight ± S.D. for the four least-weight males and four least-weight females is 0.773 ± 0.081 kg (1.704 ± 0.178 lbs). The test formulation density is reported (p. 18 of MRID 47924801) as 1.095. The minimum pyriproxyfen dosage for the 5X group on Day 0 is reported (p. 18 of MRID 47924801) as 5.848 mg/kg, and the minimum imidacloprid dosage is 110.744 mg/kg; since these values would be associated with the maximum weight kitten (1.012 kg) the [assayed?] percentages of actives can be calculated: formulation dosage was 1.15 mL x 1.095 g/mL = 1.259 g was applied to each kitten; 1.259 g ÷ 1.012 kg = 1.244 g/kg = 1244 mg/kg. The percentage of imidacloprid in the formulation was then 110.744 ÷ 1244.32 x 100% = 8.9% and the percentage of pyriproxyfen was 5.848 ÷ 1244.32 x 100% = 0.47% [According to the Certificate of Analysis on p. 68 of MRID 47924801 the percentage of imidacloprid was 9.1% and the percentage of pyriproxyfen was 0.46%].

If the percentage of imidacloprid was 9.1% then the mean formulation dosage for the four least-weight males and four least-weight females was 1.259 g ÷ 0.773 kg = 1.629 g/kg, and the mean dosage of imidacloprid was 1.629 g/kg x 0.091 = 0.148 g/kg = 148 mg/kg. Dividing this by 5 gives 29.6 mg imidacloprid/kg for a 1X dose. The mean dosage of pyriproxyfen for these same kittens was 1.629 g/kg x 0.0047 = 7.66 mg/kg, and dividing this value by 5 gives 1.53 mg pyriproxyfen/kg for a 1X dose.

The study in MRID 47924801 then supports the proposed maximum dosage rates for 91300-G (0.23 mL on a 2 lb cat = 26.8 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18.7 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20.7 mg imidacloprid/kg). For pyriproxyfen (which has very low toxicity to mammalian species), 0.23 mL 91300-G on a 2 lb cat would be a dose of 1.35 mg pyriproxyfen/kg, 0.4 mL on a 5 lb cat would be 0.95 mg pyriproxyfen/kg, and 0.8 mL on a 9 lb cat would be 1.05 mg pyriproxyfen/kg, all below the supported 1X value of 1.53 mg pyriproxyfen/kg.

5. The material in MRID 48085101 [Madsen, T. (2009) Imidacloprid + Pyriproxyfen: Addendum to Bayer Report No. 33714 (MRID 47924801) - Evaluation of the General Safety of M880. Project Number: 152/141, S07648, 33714. Unpublished study prepared by Sinclair Research Center, Inc. 9 p.] is an addendum to the report in MRID 47924801.

6. CITAB concludes that cite-all satisfies the companion animal safety data requirements (including minimum age of 8 weeks and the proposed maximum dosage rates) to support the registration of 91300-G. ✓

7. For the acute toxicity data requirements, the registrant is citing specific studies (MRID 49287704 for 870.1100 (acute oral toxicity); 49287705 for 870.1200 (acute dermal toxicity); 49287709 for 870.1300 (acute inhalation toxicity); 49287706 for 870.2400 (eye irritation); 49287707 for 870.2500 (dermal irritation); and 49287708 for 870.2600 (dermal sensitization).

8. All of these studies except 49287709 (a waiver request) have been previously reviewed and classified as acceptable (TXR 5015022, TRB memorandum for 2596-RIR dated June 27, 2014). Based on the product use pattern (application of a limited amount directly to the skin of a cat or dog), it was concluded that an inhalation study waiver is appropriate with assignment to toxicity category IV by this exposure route.

9. After a comparison of the CSFs of 91300-G and 2596-181, it is concluded that these two formulations are toxicologically similar, and the acute toxicity studies (and data waiver request) that supported the registration of 2596-181 also satisfy the acute toxicity data requirements for 91300-G. All acute toxicity (and companion animal safety) data requirements for the registration of 91300-G have been satisfied.

10. The following is the acute toxicity profile for 91300-G:

Oral LD_{50} (rat)	Tox. Category III*	Cited	EPA Reg. No. 2596-181
Dermal LD_{50} (rat)	Tox. Category IV	Cited	EPA Reg. No. 2596-181
Inhalation LC_{50}	Tox. Category IV	Waived	EPA Reg. No. 2596-181
Eye Irritation (rabbit)	Tox. Category III	Cited	EPA Reg. No. 2596-181
Skin Irritation (rabbit)	Tox. Category IV	Cited	EPA Reg. No. 2596-181
Skin Sensitization	Non-sensitizer	Cited	EPA Reg. No. 2596-181

*The oral LD_{50} is greater than 1500 mg/kg; therefore this product does not require Child-Resistant Packaging (CRP).

11. Based on the acute toxicity profile, the following is the precautionary and first aid labeling for EPA File Symbol 91300-G, as obtained from the Label Review System:

PRODUCT ID #: **091300-00003**

PRODUCT NAME: **TORC DUO™ FOR CATS**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

12. The registrant's proposed labeling under HAZARDS TO DOMESTIC ANIMALS is consistent with PR Notice 96-6.

Decision #: 506519
DP #: (429431)
PRIA
Parent DP #:
Submission #: 970511
E-Sub #: 7991

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2015

* * * Registration Information * * *

Registration: 91300-G - Torc Duo for Cats

Company: 91300 - PROMIKA, LLC

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7228

Risk Manager Reviewer: Jacquelyn Marchese JMARCHES

Sent Date: _____ PRIA Due Date: ~~23-Nov-2015~~ 12/23/15 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R301) NEW PRODUCT;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND I

Ingredients: 129099, Imidacloprid(9.1%)

129032, Pyriproxyfen(.46%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 05-Oct-2015 Due Back: _____

DP Ingredient: 129032, Pyriproxyfen

129099, Imidacloprid

DP Title: Acute Tox/Sim Clinic

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

	Assigned To	Date In	Date Out
Organization:	RD / IVB3		
Team Name:	RM 01		
Reviewer Name:	Lewis, Marianne		
Contractor Name:			

11/13/15

Last Possible Science Due Date: ~~24-Sep-2015~~

Science Due Date: _____

Sub Data Package Due Date: _____

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Marianne,
Pleave review the submitted studies and CSF in support of the new pet spot on product Torc Duo for Cats (91300-G) and note that this action have been coded an R301 - it should have the exact same studies, label and CSF as the me-tooed product 2596-180. I have included the data matrix, CSF, cover letter and label of the proposed product along with the data matrix, CSF, label, and old tox review of the me-tooed product. Please let me know if there are any discrepancies or if you have any questions.

Thank you,
Jackie
marchese.jacquelyn@epa.gov
703-347-0559

DP#: (429431) *** Studies Sent for Review *** Decision#: (506519)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49287704		Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Oral Toxicity Up and Down Procedure in Rats [Hartz Reference 146]. Project Number: P320/UDP, 37571, 2604. Unpublished study prepared by Product Safety Laboratories. 15p.	870.1100/Acute Oral Toxicity	Pass (07-Apr-2014)
49287705		Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Dermal Toxicity Study in Rats-Limit Test [Hartz Reference 146]. Project Number: P322/RAT, 37638, 2605. Unpublished study prepared by Product Safety Laboratories. 14p.	870.1200/Acute dermal toxicity	Pass (07-Apr-2014)
49287706		Lowe, C. (2013) Dermal Treatment TS# 13821: Primary Eye Irritation Study in Rabbits [Hartz Reference 146]. Project Number: P324, 37639, 2606. Unpublished study prepared by Product Safety Laboratories. 18p.	870.2400/Acute eye irritation	Pass (07-Apr-2014)
49287707		Lowe, C. (2013) Dermal Treatment TS# 13821:Primary Skin Irritation Study in Rabbits [Hartz Reference 146]. Project Number: P326, 37640, 2607. Unpublished study prepared by Product Safety Laboratories. 15p.	870.2500/Acute dermal irritation	Pass (07-Apr-2014)
49287708		Lowe, C. (2013) Dermal Treatment TS# 13821: Dermal Sensitization Study in Guinea Pigs [Hartz Reference 146]. Project Number: P328, 37641, 2608. Unpublished study prepared by Product Safety Laboratories. 23p.	870.2600/Skin sensitization	Pass (07-Apr-2014)
49287709		The Hartz Mountain Corporation (2013) Acute Inhalation Toxicity Waiver Request [Hartz Reference 146]. Unpublished study. 4p.		Pass (07-Apr-2014)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

ACUTE TOXICITY MEMORANDUM:

Subject: EPA Reg. No.: 91300-G/Torc Duo for Cats
DP Barcode: 429431
PC Code: 129032 (pyriproxyfen), 129099 (imidacloprid)

From: Marianne Lewis, Biologist
Invertebrate Vertebrate Branch 3
Registration Division (7505P)

Marianne Lewis
10/9/15

Thru: John Redden, Senior Scientist
CITAB
Registration Division (7505P)

JLR

To: Venus Eagle, PM 01
Invertebrate Vertebrate Branch 3
Registration Division (7505P)

Applicant: Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

FORMULATION FROM EPA Reg. No. 91300-G LABEL:

	% by wt.
Active Ingredient(s):	
Imidacloprid:	9.10%
Pyriproxyfen:	0.46%
Inert Ingredient(s):	90.44%
Total	100.00%

BACKGROUND: The registrant is citing specific MRID's and a waiver request (acute inhalation) for the acute toxicity data and is claiming similarity to EPA Reg. No. 2596-181 to support the reregistration of their product, EPA Reg. No. 91300-G. After reviewing the CSF's from EPA Reg. No. 2596-181 and the subject product it has been determined that these products are similar. The MRID's are as follows: 492877-04 (81-1), 492877-05 (81-2), 492877-09 (81-3 waiver), 492877-06 (81-4), 492877-07 (81-5), 492877-06 (81-6). The MRID's and waiver request were reviewed and found to be acceptable by CITAB/RD on 6/27/14. The subject product will be assigned to the following Toxicity Categories: acute oral (81-1) – III; acute dermal (81-2) – IV; acute inhalation (81-3) – IV; primary eye irritation (81-4) – III; primary dermal irritation (81-5) – IV. The subject product will be classified as a non sensitizer.

RECOMMENDATIONS:

- The subject product will be assigned the acute toxicity categories as listed above.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 91300-G is currently:

Acute Oral	III
Acute Dermal	IV
Acute Inhalation	IV
Primary Eye	III
Primary Dermal	IV
Skin Sensitization	non sensitizer

NOTE: The acute toxicity study requirements have been satisfied for the subject product.

LABELING:

ID #: 091300-G TORC DUO FOR CATS

SIGNAL WORD: **CAUTION**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear long sleeved shirt, long pants, shoes, and socks. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID:

IF SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

[Front Panel]

TORC™ DUO FOR CATS

Topical Flea Product for Cats
For Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.]

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

[See [back] [side] [other] [panel] for FIRST AID and PRECAUTIONARY STATEMENTS]
[Refer to Package Insert for Directions for Use, Storage and Disposal, and First Aid.

NET CONTENTS: X fl. oz.
[Picture of a cat in appropriate weight range on front panel to be included]

[2 to 5 lbs.:] [X] tube(s), each 0.0078 fl. oz.
[5 to 9 lbs.:] [X] tube(s), each 0.014 fl. oz.
[Over 9 lbs.:] [X] tube(s), each 0.027 fl. oz.

EPA Reg. No. 91300-NEW
EPA Est. No. XXXXX-XX-X

[Manufactured for:]
[Distributed by:]
Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

[Back Panel]

TORC™ DUO FOR CATS

Topical Flea Product for Cats

For Use ONLY on Cats 8 Weeks and Older and Weighing [2 – 5 lbs][5-9 lbs][Over 9 lbs]

READ THE ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external Use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than [2 lbs.] [5 lbs.] [9 lbs.]. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide products for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

FIRST AID	
If Swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If In Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If On Skin:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 - 20 minutes. • Call a poison control center or doctor for treatment or advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-844-685-9173.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

Side Effects: Monitor your cat after application. Side effects, although very rare, may include signs of skin irritations such as redness, scratching, or other signs of discomfort.
Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-844-685-9173.

RESTRICTIONS:

- Use only on cats or kittens 8 weeks and older.
- Do not apply to cats or kittens weighing less than [2 lbs.] [~~5 lbs.~~] [~~9 lbs.~~]
- Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger cats.
- Do not have contact or allow children to have contact with treated area until completely dry.

[Sample – Not for (Re)Sale]

[Manufactured for:]
[Distributed by:]
Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560
[Made in the USA]

[Back Panel and/or Insert]

TORC™ DUO FOR CATS

Topical Flea Product for Cats

For Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.]

READ THE ENTIRE LABEL BEFORE EACH USE
Prevent and Treat Flea Infestations

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. To prevent harm to you and your cat, read the entire label and package insert before each use. Follow all directions and precautionary statements carefully. Use ONLY on Cats 8 Weeks and Older and Weighing [2 - 5 lbs.] [5 - 9 lbs.] [Over 9 lbs.].

[INSTRUCTIONS FOR BLISTER PACK:]
[Visuals Depicting How to Open Package]

HOW TO OPEN

[OPTION 1:]

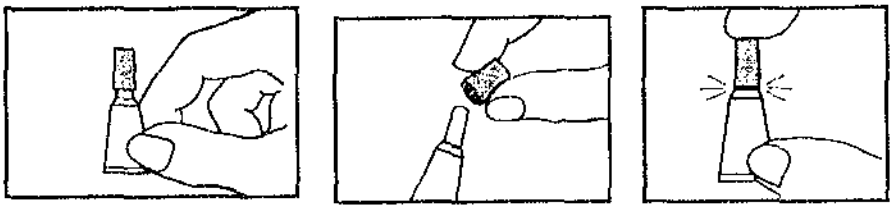
1. Being careful not to cut close to the blister cavities take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

APPLICATION INSTUCTIONS:

[Visuals Depicting How to Open Applicator Tube and Application to Animal]



HOW TO APPLY

[OPTION 1:]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes, or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

[OPTION 2:]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
3. Twist dispensing tip clockwise about half (½) turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes, or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

TORC™ DUO FOR CATS kills fleas on cats within 12 hours, which may reduce the incidence of flea allergy dermatitis (FAD) or flea bite hypersensitivity. This product prevents further flea infestation for four weeks by killing reinfesting fleas within 2 hours.

TORC™ DUO FOR CATS kills fleas, eggs and larvae ~~in the cat's surroundings when contacted by a treated cat~~ and effectively controls all flea life-cycle stages for ~~lasting~~ control of flea populations.

TORC™ DUO FOR CATS is waterproof and is effective on your cat, even after shampoo treatment, swimming or exposure to rain or sunlight.

To ~~optimize treatment and prevention of fleas~~, use TORC™ DUO FOR CATS monthly.

Use monthly to control and prevent fleas.

[OPTIONAL GRAPHICS/ICONS/PICTURES – COLOR MAY CHANGE]

[For Chemical Emergency, Spills, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night within USA and Canada: 1-800-424-9300 CCN712312 or +1 703-527-3887 (collect calls accepted)]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. **Pesticide Disposal and Container Handling:** Nonrefillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES,** and **LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Promika, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Promika, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Promika, LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Promika, LLC disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Promika, LLC election, the replacement of product.]

[Label on Individual Tube]

TORC™ DUO FOR CATS

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]

2 to 5 lbs. - 0.0078 fl. oz. ≥ 8 wks age
5 to 9 lbs. - 0.014 fl. oz. ≥ 8 wks "
Over 9 lbs. - 0.027 fl. oz. ≥ 8 wks "

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN
CAUTION
Read Entire Label Before Use

EPA Reg. No. 91300-NEW
[Lot No. is heat stamped in tube crimp – required on each]

NOTE TO REVIEWER: [(Brackets and parentheses indicated alternate language)]

OPTIONAL MARKETING CLAIMS [May appear on any panel/insert]

[Fleas]

- Kills fleas (Ctenocephalides sp.) on your cat and in its environment
- Kills fleas
- Month long flea protection
- Kills fleas within 12 hours of application
- Kills fleas for up to [4 weeks] [1 month]
- Kills fleas which may cause flea allergy dermatitis and flea bite anemia
- Effective against fleas that may cause flea allergy dermatitis and flea bite anemia
- Kills fleas that may cause transmission of tapeworms
- TORC™ DUO FOR CATS is effective for the prevention and treatment of fleas on cats
- Prevent further flea infestations for [4 weeks] [1 month]
- Protects against reinfesting fleas for [4 weeks] [1 month] [30 days]
- Kills fleas on cats within 12 hours to prevent infestations for [4 weeks] [1 month]
- Kills fleas before they lay eggs
- Direct contact to TORC™ DUO FOR CATS [disrupts] [stops] [kills] [controls] larval flea stages in the cat's environment
- Kills all larval stages of fleas
- Targets all life stages of fleas
- [Prevents] [Stops] flea eggs and flea larvae from developing into biting adults
- Breaks the flea life cycle

- Triple flea protection: kills adults, larvae, and eggs
- Flea adulticide, larvicide, and ovicide
- Multi-stage flea control
- Flea protection
- Controls existing fleas and flea eggs to prevent future flea infestations
- The Insect growth regulator (IGR) kills flea eggs and prevents reinfestation

[Other]

- For use on cats and kittens 8 weeks of age and older
- TORC™ DUO FOR CATS contains imidacloprid [, in conjunction with [an/the] [insect growth regulator] [IGR] [pyriproxyfen]]
- One topical application remains effective for [4 weeks] [a month]
- Convenient topical solution
- Easy-to-apply [monthly] [topical solution]
- Use year round for best results
- A monthly topical application for cats 8 weeks of age or older
- Starts working through contact
- Remains effective after bathing and/or swimming
- Continues to kill fleas even if your cat gets wet
- Water resistant
- Waterproof
- Fragrance-free
- Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Advantage® II Cat
- Advantage® II is a registered trademark of Bayer Healthcare LLC Animal Health Division
- TORC™ DUO FOR CATS is not manufactured, or distributed by Bayer Healthcare LLC Animal Health Division, seller of Advantage® II Cats
- 1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose
- First month, second month, third month, fourth month, fifth month, sixth month
- Value pack: [1] [2] [3] [4] [5] [6] month supply
- Apply monthly [every 30 days] [every 4 weeks]
- Convenient [applicator]
- Easy to use [applicator]
- Direct to your cat's skin
- Simple to [handle/apply]
- ~~Made in the U.S.A.~~

Treated area may appear wet for up to 24 hours, following application
As a reminder for applied treatments, use the following system:

First Dose _____
Second Dose _____
Third Dose _____
Fourth Dose _____
Fifth Dose _____
Sixth Dose _____

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Promika, LLC 1204 Village Market Place, #273, Morrisville, NC 27560; 919-946-8294	**91300-NEW**
Active Ingredient(s) and/or representative test compound(s) **Imidacloprid and pyriproxyfen**	Date **June 29, 2015**
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) **Indoor non-food**	Product Name **TORC™ DUO for Cats**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature	Date	Typed or Printed Name and Title
Brooke Hedrick	**6/29/2015**	**Brooke Hedrick** **Regulatory and Project Management**

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Promika

U.S. Registered Mail

June 30, 2015

Hartz Mountain Corporation
Attention: Regulatory Manager
400 Plaza Drive
Secaucus, NJ 07094

Subject: **Offer to Pay Compensation Under FIFRA Section 3(c)(1)(F)**
Promika, LLC Proposed Product TORC™ DUO for Cats and TORC™ DUO for Dogs ("PRODUCTS")

To Whom It May Concern:

As required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c)(1)(F), and implementing regulations at 40 CFR Part 152 Subpart E, Promika, LLC ("Promika") hereby notifies Hartz Mountain Corporation, EPA Company Number 2596 ("COMPANY") that it intends to selectively cite data regarding imidacloprid and pyriproxyfen on file with the U.S. Environmental Protection Agency ("USEPA" or "Agency") related to your end-use products containing imidacloprid and pyriproxyfen to support the USEPA registration of the above-referenced end-use PRODUCTS containing the same active ingredients.

According to the USEPA's Listing of Pesticide Data Submitters (dated 3/31/2015), Promika has identified COMPANY as an Original Data Submitter who has end-use product data on file with the Agency for the active ingredients imidacloprid and pyriproxyfen.

Promika hereby notifies COMPANY:

1. That it is the intent of Promika to submit to the USEPA an application for pesticide registration for the end-use PRODUCTS containing the active ingredients imidacloprid and pyriproxyfen;

2. That Promika's offers to pay compensation regarding data, as appropriate, to COMPANY, with regard to the approval of this registration application, to the extent required by FIFRA Section 3(c)(1)(F); and

3. Promika offers to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any data.

If COMPANY intends to request compensation for the use of COMPANY's data, with regard to the approval of Promika's registration application, Promika respectfully requests that COMPANY indicate, by return correspondence, the amount and terms of such requested compensation, and the amount of any compensation previously received by COMPANY from the use of these data from other parties for each Study for which compensation is requested.

Table of Studies Submitted by COMPANY and Selectively Cited by Promika:

MRID	Citation
49287501	McGarvey, E. (2013) Product Chemistry Self-Certification Per PR Notice 98-1 [Hartz Reference 145]. Project Number: CPD/2013/4. Unpublished study prepared by The Hartz Mountain Corporation. 7p.
49287502	McGarvey, E. (2013) (Product Chemistry Group A: Hartz Reference 145). Unpublished study prepared by The Hartz Mountain Corporation. 10p.
49287503	McGarvey, E. (2013) Product Chemistry Enforcement Analytical Method [Hartz Reference 145]. Project Number: 13/08. Unpublished study prepared by the Hartz Mountain Corporation. 49p.
49287504	Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Oral Toxicity Up and Down Procedure in Rats. Project Number: 2604, 37571, P320/UDP. Unpublished study prepared by Product Safety Laboratories. 15p.
49287505	Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Dermal Toxicity Study in Rats- Limit Test. Project Number: 2605, 37638, P322/RAT. Unpublished study prepared by Product Safety Laboratories. 14p.
49287506	Lowe, C. (2013) Dermal Treatment TS# 13821: Primary Eye Irritation Study in Rabbits. Project Number: 2606, 37639, P324. Unpublished study prepared by Product Safety Laboratories. 18p.
49287507	Lowe, C. (2013) Dermal Treatment TS# 13821: Primary Skin Irritation Study in Rabbits. Project Number: 2607, 37640, P326. Unpublished study prepared by Product Safety Laboratories. 15p.
49287508	Lowe, C. (2013) Dermal Treatment TS# 13821: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 2608, 37641, P328. Unpublished study prepared by Product Safety Laboratories. 23p.
49287509	The Hartz Mountain Corporation (2013) Chemistry Data Waivers: Acute Inhalation Toxicity Waiver Request [Hartz Reference 145]. Unpublished study prepared by The Hartz Mountain Corporation. 4p.
49287701	McGarvey, E. (2013) Product Chemistry Self-Certification Per PR Notice 98-1 [Hartz Reference 146]. Project Number: CPD/2013/4. Unpublished study prepared by the Hartz Mountain Corporation. 7p.
49287702	McGarvey, E. (2013) Product Chemistry [Hartz Reference 146]. Unpublished study prepared by The Hartz Mountain Corporation. 10p
49287703	McGarvey, E. (2013) Product Chemistry Enforcement Analytical Method [Hartz Reference 146]. Unpublished Study Prepared by the Hartz Mountain Corporation. 49p. [DUPLICATE OF MRID 49287903]
49287704	Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Oral Toxicity Up and Down Procedure in Rats [Hartz Reference 146]. Project Number: P320/UDP, 37571, 2604. Unpublished study prepared by Product Safety Laboratories. 15p.
49287705	Lowe, C. (2013) Dermal Treatment TS# 13821: Acute Dermal Toxicity Study in Rats-Limit Test [Hartz Reference 146]. Project Number: P322/RAT, 37638, 2605. Unpublished study prepared by Product Safety Laboratories. 14p.
49287706	Lowe, C. (2013) Dermal Treatment TS# 13821: Primary Eye Irritation Study in Rabbits [Hartz Reference 146]. Project Number: P324, 37639, 2606. Unpublished study prepared by Product Safety Laboratories. 18p.

Promika

49287707	Lowe, C. (2013) Dermal Treatment TS# 13821:Primary Skin Irritation Study in Rabbits [Hartz Reference 146]. Project Number: P326, 37640, 2607. Unpublished study prepared by Product Safety Laboratories. 15p.
49287708	Lowe, C. (2013) Dermal Treatment TS# 13821: Dermal Sensitization Study in Guinea Pigs [Hartz Reference 146]. Project Number: P328, 37641, 2608. Unpublished study prepared by Product Safety Laboratories. 23p.
49287709	The Hartz Mountain Corporation (2013) Acute Inhalation Toxicity Waiver Request [Hartz Reference 146]. Unpublished study. 4p.

Promika requests a response from COMPANY within 90 days from the date of this letter. If Promika does not receive a response within 90 days, it will understand that no data compensation is requested by COMPANY.

If you have any questions, please contact me at 984-664-9806 or Brooke.Hedrick@CSELifeScience.com.

Sincerely,

Brooke Hedrick
Promika, LLC

Form Approved. OMB No. 2070-0060. Approval expires 5-31-98

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Promika, LLC **1204 Village Market Place, #273** **Morrisville, NC 27560**	91300-NEW
	Product Name Torc™ Duo for Cats
	Date of Confidential Statement of Formula ***(EPA Form 8570-4)*** June 29, 2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):
Imidacloprid and Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

[X] (A) An accurate Confidential Statement of Formula (*EPA FORM 8570-4*) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR

[ ] (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

Active Ingredient	Product Name	Registration Number
Imidacloprid	[redacted]	
Pyriproxyfen		
Pyriproxyfen		
Pyriproxyfen		

Signature	Name and Title	Date
Brooke Hedrick	Brooke Hedrick Regulatory & Project Management	June 29, 2015

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

Product ingredient source information may be entitled to confidential treatment

*U.S. GPO: 1995-388-820/20413

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Promika, LLC 1204 Village Market Place, #273, Morrisville, NC 27560; 919-946-8294	EPA Registration Number/File Symbol 91300-G
Active Ingredient(s) and/or representative test compound(s) Imidacloprid and pyriproxyfen	Date Oct. 6, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name TorcTM Duo for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2015.10.06 10:21:30 -04'00'	Date Oct. 6, 2015	Typed or Printed Name and Title Ann M. Tillman, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: Sept. 15, 2015	**EPA Reg. No./File Symbol: 91300-G**	**Page 1 of 2**
Applicant's/Registrant's Name and Address: Promika, LLC 1204 Village Market Place, #237 Morrisville, NC 27560	**Product Name:** TORC DUO™ for Cats	
Ingredients: Imidacloprid and Pyriproxyfen		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.310: Product Chemistry Data Requirements					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A: Product Identity and Composition	49658401	Promika, LLC.	OWN	
830.1800	Enforcement analytical method	49287703	The Hartz Mountain Corp.	PAY	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B: Physical and Chemical Properties	49658202	Promika, LLC	OWN	See TORC DUO™ for Dogs
830.6317, 830.6320	Storage Stability & Corrosion Characteristics	Generated post registration	Promika, LLC	OWN	
§ 158.500: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49287704	The Hartz Mountain Corp.	PAY	
870.1200	Acute dermal toxicity	49287705	The Hartz Mountain Corp.	PAY	
870.1300	Acute inhalation toxicity	49287709	The Hartz Mountain Corp.	PAY	
870.2400	Primary eye irritation	49287706	The Hartz Mountain Corp.	PAY	
870.2500	Primary dermal irritation	49287707	The Hartz Mountain Corp.	PAY	
870.2600	Dermal sensitization	49287708	The Hartz Mountain Corp.	PAY	

Signature:	Name and Title:	Date:
Brooke Hedrick	**Brooke Hedrick** **Regulatory & Project Management**	**Sept. 15, 2015**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: Sept. 15, 2015	**EPA Reg. No./File Symbol: 91300-G**	**Page 2 of 2**
Applicant's/Registrant's Name and Address: Promika, LLC 1204 Village Market Place, #237 Morrisville, NC 27560	**Product Name:** TORC DUO™ for Cats	

Ingredients: Imidacloprid and Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
870.7200	Companion Animal Safety	Cite-all		PAY	
§ 158.400: Efficacy Data Requirements					
810.3300	Product Performance	Cite-all		PAY	
Generic Data Requirements					
Torc Duo for Cats qualifies for Formulator's Exemption for imidacloprid and pyriproxyfen generic data requirements.					

Signature:	Name and Title:	Date:
Brooke Hedrick	**Brooke Hedrick** **Regulatory & Project Management**	**Sept. 15, 2015**

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Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: June 29, 2015	EPA Reg. No./File Symbol: 91300-NEW	Page 1 of 3
Applicant's/Registrant's Name and Address: Promika, LLC 1204 Village Market Place, #237 Morrisville, NC 27560	**Product Name:** TORC DUO™ for Cats	

Ingredients: Imidacloprid and Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.310: Product Chemistry Data Requirements					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A: Product Identity and Composition	49658401 49287702	Promika, LLC The Hartz Mountain Corp.	OWN PAY	
830.1800	Enforcement analytical method	49287703	The Hartz Mountain Corp.	PAY	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B: Physical and Chemical Properties	49658202 49287701	Promika, LLC The Hartz Mountain Corp.	OWN PAY	See TORC DUO™ for Dogs
830.6317, 830.6320	Storage Stability & Corrosion Characteristics	Generated post registration	Promika, LLC	OWN	
§ 158.500: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49287704	The Hartz Mountain Corp.	PAY	
870.1200	Acute dermal toxicity	49287705	The Hartz Mountain Corp.	PAY	
870.1300	Acute inhalation toxicity	49287709	The Hartz Mountain Corp.	PAY	
870.2400	Primary eye irritation	49287706	The Hartz Mountain Corp.	PAY	
870.2500	Primary dermal irritation	49287707	The Hartz Mountain Corp.	PAY	
870.2600	Dermal sensitization	49287708	The Hartz Mountain Corp.	PAY	

Signature:	Name and Title:	Date:
Brooke Hedrick	**Brooke Hedrick** **Regulatory & Project Management**	**June 29, 2015**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: June 29, 2015	**EPA Reg. No./File Symbol: 91300-NEW**	**Page 2 of 3**
Applicant's/Registrant's Name and Address: Promika, LLC 1204 Village Market Place, #237 Morrisville, NC 27560	**Product Name:** TORC DUO™ for Cats	

Ingredients: Imidacloprid and Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Cats with Imidacloprid (Bay t 7391) Spot-On	43679501	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Cats	43679502	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Six Week Old Kittens	44157301	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number	44157302	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Cats	44179802	Bayer Animal Health	OLD	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, Adult Cats	45097001	Bayer Animal Health	OLD	
870.7200	Evaluation of the General Safety of M880	47924801	Bayer Animal Health	PAY	
870.7200	Imidacloprid + Pyriproxyfen: Addendum to Bayer Report No. 33714 (MRID 47924801) - Evaluation of the General Safety of M880	48085101	Bayer Animal Health	PAY	
§ 158.400: Efficacy Data Requirements					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats	43679503	Bayer Animal Health	OLD	
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats	43679504	Bayer Animal Health	OLD	

Signature: Brooke Hedrick	**Name and Title:** **Brooke Hedrick** **Regulatory & Project Management**	**Date:** **June 29, 2015**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

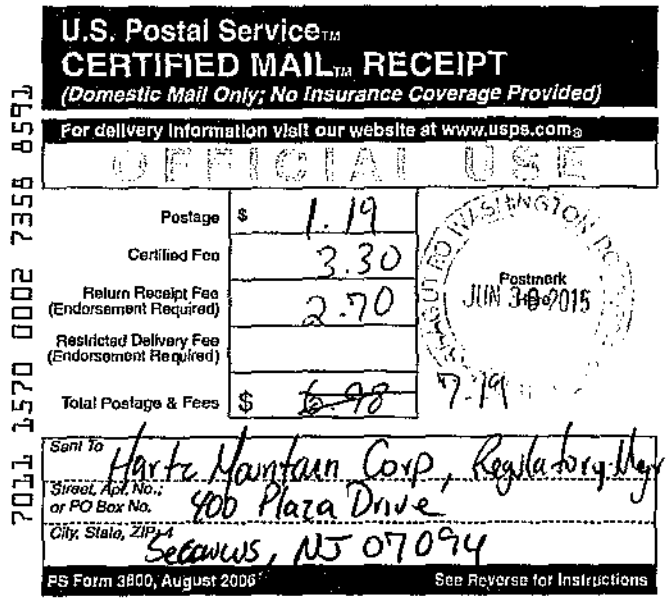
Data Matrix

Date: June 29, 2015	**EPA Reg. No./File Symbol: 91300-NEW**	**Page 3 of 3**
Applicant's/Registrant's Name and Address: Promika, LLC 1204 Village Market Place, #237 Morrisville, NC 27560	**Product Name:** TORC DUO™ for Cats	
Ingredients: Imidacloprid and Pyriproxyfen		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
810.3300	Efficacy Evaluation of BAY t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Adult Fleas and Flea Eggs on Cats	43794101	Bayer Animal Health	OLD	
810.3300	Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) 10% for Control of the Cat Flea (C. felis) in Domestic Cats	43794102	Bayer Animal Health	OLD	
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs	44256901	Bayer Animal Health	OLD	
810.3300	Imidacloprid-Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs	44256902	Bayer Animal Health	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs	44256903	Bayer Animal Health	OLD	
810.3300	Nylar 50 (percent) Concentrate: Product Performance/Efficacy Reports	45086801	McLaughlin Gormley King Company	OLD	

Signature:	Name and Title:	Date:
Brooke Hedrick	Brooke Hedrick Regulatory & Project Management	June 29, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ■ Agency Internal Use Copy ☐ Public File Copy



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CERTIFIED MAIL™ RECEIPT
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For delivery information visit our website at www.usps.com®
OFFICIAL USE
Postage $ 1.19
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Return Receipt Fee (Endorsement Required) 2.70
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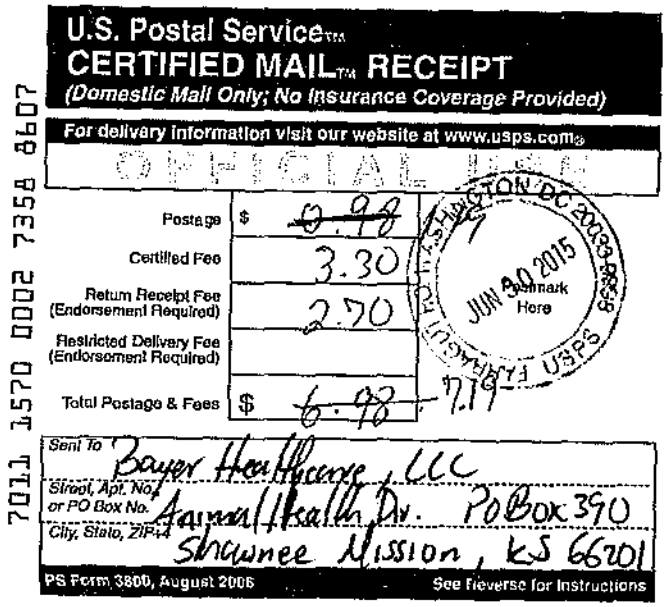
Total Postage & Fees $ ~~6.98~~ 7.19
Postmark JUN 30 2015
Sent To Hartz Mountain Corp, Regulatory Mgr
Street, Apt. No.; or PO Box No. 400 Plaza Drive
City, State, ZIP+4 Secaucus, NJ 07094
PS Form 3800, August 2006 See Reverse for Instructions
7011 1570 0002 7358 8591



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CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)
For delivery information visit our website at www.usps.com®
OFFICIAL USE
Postage $ ~~0.98~~
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Sent To Bayer Healthcare, LLC
Street, Apt. No.; or PO Box No. Farmer Health Dr. PO Box 390
City, State, ZIP+4 Shawnee Mission, KS 66201
PS Form 3800, August 2006 See Reverse for Instructions
7011 1570 0002 7358 8607

Completion of 21-Day Content Screen

PM- 1

EPA Reg. #(File Symbol) 91300-G

Decision # D_____

Data package delivered to you on 7/20/15.
(date)

Jacket/Mini-jacket will be transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

21-Day Screen Completed by Contractor

21-Day Expires on 7/22/15

Jacket # 91300-G
MRID# 496584

Content Screen: Recommend to **Pass**/Fail

11-3 Review: **Pass**/Fail/NA

Overall Status: Recommend to **Pass**/Fail

Transfer This Jacket to:

Steve Schaible

01

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 02, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PROMIKA, LLC
1204 VIILAGE MARKET PLACE #273
MORRISVILLE, NC 27560

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 01-JUL-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

o

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

06-Aug-2015
3:34 PM
Dillard, Sylvia

Requested by : Marchese, Jacquelyn

Barcode : 34238

Agency : EPA Office : OCSPP Program : OPP
Division : RD Branch : IVB3

Requested on 06-Aug-2015 at 03:34 PM

Group Num: 342196

Jacket Barcode	Regulatory Case File #	Vol/Tot	Location	Status
9302481	91300-E	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (02-Jul-2015)
9302482	91300-G	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (02-Jul-2015)

Total # of jackets requested : 2

Completed: SD Date: 8-6-15 Time: 8:35

Vernus/Jackie - Leaving you the jackets in case Jim Messina calls on Friday.

Thx S.

Marchese, Jacquelyn

TRANSFER JACKET FORM

Transfer This Jacket To: Jackie Marchese

Jacket #: 91300-G

This jacket was transferred from: Venus

Date: 8-6-15 SD

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

20-Jul-2015
2:56 PM
Adams, Teretha

Requested by : Eagle, Venus

Barcode : 20512

Agency : EPA Office : OCSPP Program : OPP
Division : RD Branch : IVB3

Requested on 20-Jul-2015 at 02:56 PM

Group Num: 341149

c/o

Jacket Barcode	Regulatory Case File #	Vol/Tot	Location	Status
9302481	91300-E	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (02-Jul-2015)
9302482	91300-G	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (02-Jul-2015)

Total # of jackets requested : 2

Completed: TA Date: 7/20/15 Time: 2:56

Eagle, Venus

E-SUBMISSION

Memorandum

91300-XX
waiting for admin 7/13/15
cat pet product

Date: 7/7/15

To: PM 07, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

01

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 7/1/15

Experts In-Processing Signature: MP Date 7/7/15 Fee Paid: Yes ✓

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 91300-G	EPA Receipt Date: 7/1/15

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)	X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) non-food (yes: X; no:)			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) (yes: ; no:)			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)	X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) (yes: X; no:)			
	b) Cite-All (Fee category experts use) (yes: ; no:)			
	c) Applicant owns all data (Fee category experts use) (yes: ; no:)			
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**	X		
7	**Is the data package consistent with PR Notice 86-5**	X		
8	**Notice of Filing included with petitions**			X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

Required forms are complete

Inerts. Pass

Inerts are approved for non-food use

II-3: Pass

MRID 49L584 (e-sub.)

Status: Pass

KC 7/15/2015

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 6, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-506519
EPA File Symbol or Registration Number: 91300-G
Product Name: Torc Duo for Cats
EPA Receipt Date: 01-Jul-2015
EPA Company Number: 91300
Company Name: PROMIKA, LLC

BROOKE HEDRICK
PROMIKA, LLC
1204 VILLAGE MARKET PLACE, #273
MORRISVILLE, NC 27560

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R301

NEW PRODUCT;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;SELECTIVE DATA CITATION ONLY FOR DATA ON PRODUCT CHEMISTRY / ACUTE TOXICITY / PUBLIC HEALTH PEST EFFICACY, WHERE APPLICANT DOES NOT OWN ALL REQUIRED DATA NOR HAS AUTHORIZATION LETTER FROM DATA OWNER;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{970511q~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 1

Receipt No. S- 970511

EPA File Symbol/Reg. No. 91300-G

Pin-Punch Date: 7/1/2015

This item is NOT subject to FFS action.

Action Code:

Requested: R301

Granted: R301

Amount Due: $ 1806.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: [signature] Date: 7/6/15

Remarks:

R 300 and 301

100% identical (repack): YES or (NO) (circle one)
{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	✓	
830.1650	Description of formulation process	✓	
830.1670	Discussion on the formation of impurities	✓	
830.1700	Preliminary analysis		
830.1750	Certified limits (158.345)	✓	
830.1800	Enforcement analytical method	✓	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	✓	
830.6303	Physical State	✓	
830.6304	Odor	✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓	
830.6315	Flammability	✓	
830.6316	Explodability		
830.6317	Storage stability	✓	
830.6319	Miscibility	✓	
830.6320	Corrosion Characteristics	✓	
830.6321	Dielectric Breakdown voltage	✓	
830.7000	pH	✓	
830.7100	Viscosity	✓	
830.7300	Density	✓	

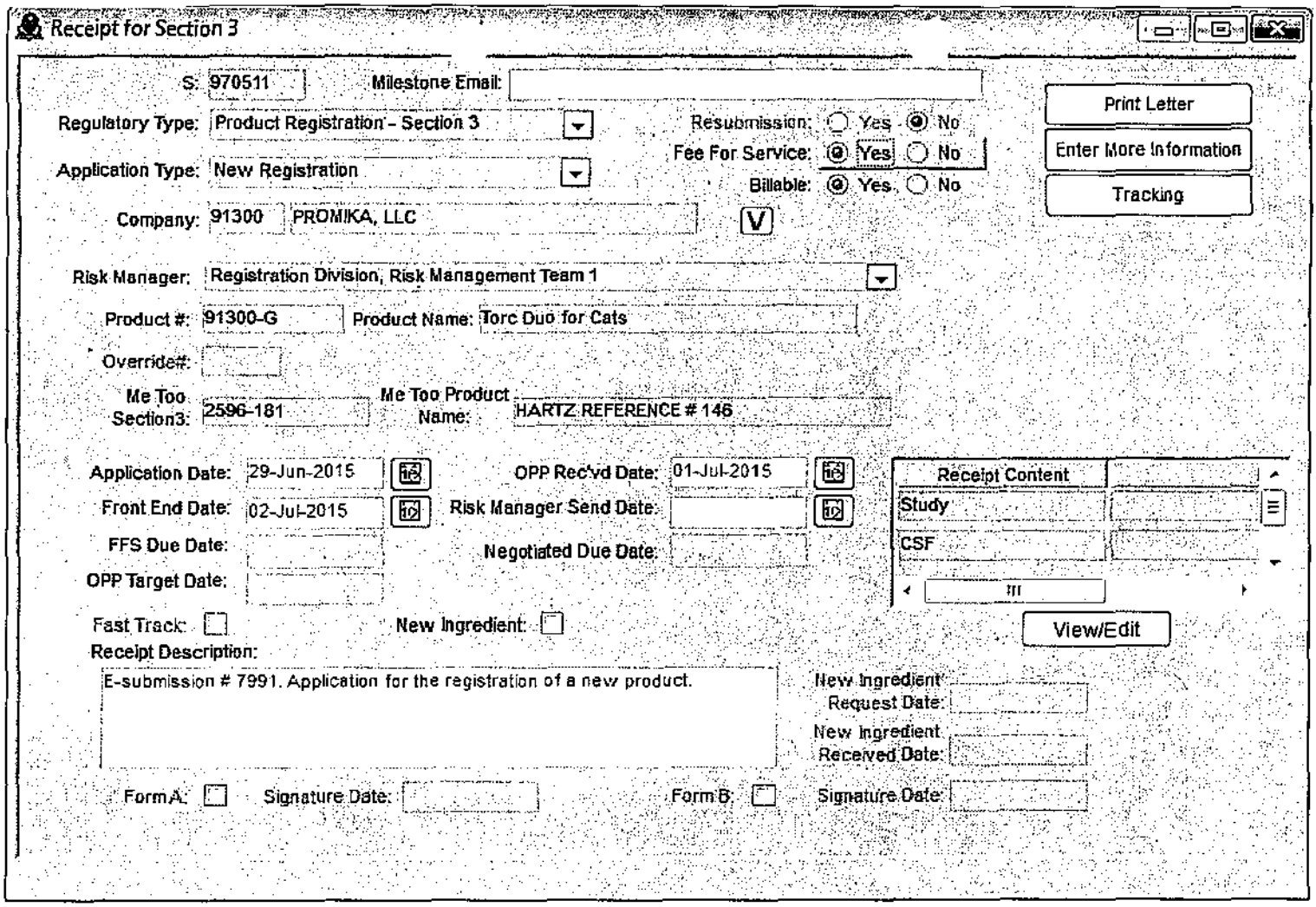
R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy - which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets	✓		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			


Receipt for Section 3
S: 970511
Milestone Email:
Regulatory Type: Product Registration - Section 3
Resubmission: Yes No
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 91300 PROMIKA, LLC
Risk Manager: Registration Division, Risk Management Team 1
Product #: 91300-G
Product Name: Torc Duo for Cats
Override#:
Me Too Section3: 2596-181
Me Too Product Name: HARTZ REFERENCE # 146
Application Date: 29-Jun-2015
OPP Rec'vd Date: 01-Jul-2015
Front End Date: 02-Jul-2015
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
E-submission # 7991. Application for the registration of a new product.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

From: Nicola Cowen
To: Nicola Cowen
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Saturday, June 27, 2015 10:46:30 AM

-----Original Message-----
From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Friday, June 26, 2015 4:02 PM
To: Brooke Hedrick
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25M1FA8U
Agency Tracking ID: 74828062309
Transaction Type: Sale
Transaction Date: 06/26/2015 04:02:11 PM EDT

Account Holder Name: Brooke Hedrick

Transaction Amount: $1,806.00
Billing Address: 1204 Village Market Place, #273
City: Morrisville
State/Province: NC
Zip/Postal Code: 27560
Country: USA
Card Type: Visa
Card Number: **********4032

Registration Number:
Company Name: Promika, LLC
Company Number: 91300
Action Code: R301

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.
71300-G

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUL -1 2015		

Do Not Write Comments, Formulas, or Parts of Formula on This Envelope

NOTE

It shall be unlawful for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

FORM 9-12
(REV. 2-80)

Pages 85-91 Confidential Statement of Formula may be entitled to confidential treatment